

Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants

SOPP 8101.1

Appendix 3

Example of the Cover Sheet Used for Distributing the Official Meeting Summary

Our Reference: *tracking #*
(*IND, BLA, CRMTS, etc.*)

Applications Division name
Telephone: (301)827-xxxx

Requestors name
Requestor's affiliation
Requestor's address
city, state zip code

Dear *Requestor*:

Attached is a copy of the memorandum summarizing your *date, type* meeting with CBER. Please note that although cited as attachments to the summary, we have not included copies of materials which you supplied. This memorandum constitutes the official record of the meeting.

If you have any questions, please contact *Point of Contact* at *telephone number*.

Sincerely yours,

signature block
Center for Biologics
Evaluation and Research

Meeting Summary Transmittal